

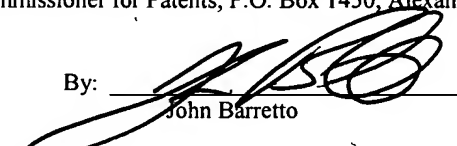


John

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Lawrence Boni et al.	Examiner: Kishore, G. S.
Serial No: 10/696,389	Art Unit: 1615
Filed: October 29, 2003	Confirmation No.: 6398
For: Sustained Release of Antiinfectives	Attorney Docket No. TRA-008.01

Commissioner for Patents
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June 21, 2006 Date of Signature and Mail Deposit	By:  John Barretto

SUPPLEMENTARY INFORMATION DISCLOSURE STATEMENT

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to the Applicants and/or their attorney to be in compliance with the requirements of 37 CFR § 1.56.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached Form 1449.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that the cited documents are material or constitute "prior art." If the Examiner applies the listed documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under

United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the referenced documents be applied against the claims of the present application.

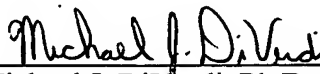
Under 37 C.F.R. § 1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits; therefore, no fee is believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fees as required to our **Deposit Account No. 06-1448**, **Reference: TRA-008.01.**

Should there be any questions after reviewing this paper, the Examiner is invited to contact the undersigned at (617) 832-1753.

Respectfully Submitted,

Date: June 21, 2006

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete If Known		
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			Examiner Name	Kishore, G. S.	
Sheet	1	of	5	Attorney Docket Number	TRA-008.01

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA*	US-4,451,447	05-29-1984	Kaplan et al.	
	AB*	US-4,767,874	08-30-1988	Shima et al.	
	AC*	US-5,945,122	08-31-1999	Abra et al.	
	AD*	US-5,665,383	09-09-1997	Grinstaff et al.	
	AE*	US-6,090,407	07-18-2000	Knight et al.	
	AF*	US-6,451,784-B1	09-17-2002	Placke et al.	
	AG*	US-6,419,901-B2	07-16-2002	Placke et al.	
	AH*	US-6,147,060	11-14-2000	Zasloff et al.	
	AI*	US-6,440,393-B2	08-27-2002	Waldrep et al.	
	AJ*	US-6,599,912	07-29-2003	Au et al.	
	AK*	US-6,511,676	01-28-2003	Boulikas	
	AL*	US-5,795,589	08-18-1998	Mayer et al.	
	AM*	US-20020187105-A1	12-12-2002	Zou et al.	
	AN*	US-5,049,389	09-17-1991	Radhakrishnan	
	AO*	US-6,045,828	04-04-2000	Bystrom et al.	
	AP*	US-5,875,776	03-02-1999	Vaghefi	
	AQ*	US-5,006,343	04-09-1991	Benson et al.	
	AR*	US-5,000,958	03-19-1991	Fountain et al.	
	AS*	US-4,933,121	06-12-1990	Law et al.	
	AT*	US-5,849,490	12-15-1998	Schonwetter et al.	
	AU*	US-5,320,906	06-14-1994	Eley et al.	
	AV*	US-6,352,996	03-05-2002	Cao et al.	
	AW*	US-20030059375-A1	03-27-2003	Perez-Soler et al.	
	AX*	US-5,459,127	10-17-1995	Felgner et al.	
	AY*	US-4,372,949	02-08-1983	Kodama et al.	
	AZ*	US-4,396,630	08-02-1983	Riedl et al.	
	AA1*	US-4,394,448	07-19-1983	Szoka, Jr. et al.	
	AB1*	US-5,178,876	01-12-1993	Khokhar et al.	
	AC1*	US-5,334,761	08-02-1994	Gebeyehu et al.	
	AD1*	US-4,693,999	09-15-1987	Axelsson et al.	
	AE1*	US-5,543,152	08-06-1996	Webb et al.	
	AF1*	US-5,279,833	01-18-1994	Rose	
	AG1*	US-5,264,618	11-23-1993	Felgner et al.	
	AH1*	US-5,753,613	05-19-1998	Ansell et al.	
	AI1*	US-4,895,719	01-23-1990	Radhakrishnan et al.	
	AJ1*	US-5,077,056	12-31-1991	Bally et al.	
	AK1*	US-5,741,516	04-21-1998	Webb et al.	
	AL1*	US-5,049,388	09-17-1991	Jack V. Knight	
	AM1*	US-5,616,334	04-01-1997	Janoff et al.	
	AN1*	US-5,641,662	06-24-1997	Robert J. Debs	
	AO1*	US-5,756,353	05-26-1998	Debs	
	AP1*	US-6,843,942-A1	01-18-2005	Katinger et al.	
	AQ1*	US-4,895,452	01-23-1990	Yiournas et al.	

Examiner Signature		Date Considered	
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		Country Code ² -Number ⁴ -Kind Code ³ (if known)	MM-DD-YYYY			
	BA	GB-2145107-A	03-20-1985			
	BB	WO-86/06959	12-04-1986			
	BC	WO-91/16882	11-14-1991			
	BD	WO-96/19199	06-27-1996			
	BE	WO-93/12240	06-24-1993			
	BF	EP-0069307-A	01-12-1983		Abstract	
	BG	WO-00/29103	05-25-2000			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
✓	CA	Niven, Ralph et al., Nebulization of Liposomes. I. Effects of Lipid Composition, Report, pp. 1127-1133.		
✓	CB	Katare, O.P., et al., Enhanced <i>in vivo</i> Performance of Liposomal Indomethacin Derived From Effervescent Granule Based Proliposomes, J. Microencapsulation, 1995, Vol. 12, No. 5, pp. 487-493.		
✓	CC	Petkowicz, Jozefa, et al., Hypoglycemic Effect of Liposome-Entrapped Insulin Administered by Various Routes into Normal Rats, Pol. J. Pharmacol. Pharm., 1989, 41, pp. 299-304.		
✓	CD	Comis, "Carboplatin in the Treatment of Non-Small Cell Lung Cancer: a Review," <i>Oncology</i> , 1993 Nov.; 50 (2): 37-41. (Abstract)		
✓	CE	A.Bargoni, R. Cavalli, G.P. Zara, A. Fundaro, O. Caputo, M.R. Gasco (2001) Transmucosal transport of tobramycin incorporated in solid lipid nanoparticles (SLN) after duodenal administration to rats. Part II - Tissue distribution. <i>Pharmacological Research</i> 43(5): 497-502.		
✓	CF	J. Lagace, M. Dubreuil, S. Montplaisir (1991) Liposome-encapsulated antibiotics: preparation, drug release and antimicrobial activity against <i>Pseudomonas aeruginosa</i> . <i>Journal Microencapsulation</i> 8(1): 53-61.		
✓	CG	L.S. Ramsammy, G.J. Kaloyanides (1988) The effect of gentamicin on the biophysical properties of phosphatidic acid liposomes is influenced by the O-C=O group of the lipid. <i>Biochemistry</i> 27: 8249-8254.		
✓	CH	C. Dees, R.D. Schultz (1990) The mechanism of enhanced intraphagocytic killing of bacteria by liposomes containing antibiotics. <i>Veterinary Immunology and Immunopathology</i> 24: 135-146.		
✓	CI	C. Beaulac, S. Sachetelli, J. Lagace (1999) Aerolization of low phase transition temperature liposomal tobramycin as a dry powder in an animal model of chronic pulmonary infection caused by <i>Pseudomonas aeruginosa</i> . <i>Journal Drug Targeting</i> 7(1): 33-41.		
✓	CJ	J.F. Marier, J.L. Brazier, J. Lavigne, M.P. Ducharme (2003) Liposomal tobramycin against pulmonary infections of <i>Pseudomonas aeruginosa</i> : a pharmacokinetic and efficacy study following single and multiple intratracheal administrations in rats. <i>Journal Antimicrobial Chemotherapy</i> 52: 247-252.		
Examiner Signature				Date Considered

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CK	E.A. Poyner, H.O. Alpar, M.R.W. Brown (1993) Preparation, properties and the effects of free and liposomal tobramycin on siderophore production by <i>Pseudomonas aeruginosa</i> . <i>Journal Antimicrobial Chemotherapy</i> 34: 43-52.
CL	A. Omri, M. Ravaoarinoro, M. Poisson (1995) Incorporation, release and in vitro antibacterial activity of liposomal aminoglycosides against <i>Pseudomonas aeruginosa</i> . <i>Journal Antimicrobial Chemotherapy</i> 36: 631-639.
CM	C. Beaulac, S. Clement-Major, J. Hawari, J. Lagace (1997) In vitro kinetics of drug release and pulmonary retention of microencapsulated antibiotic in liposomal formulations in relation to the lipid composition. <i>Journal Microencapsulation</i> 14(3): 335-348.
CN	P. Demaeyer, E.M. Akodad, E. Gravet, P. Schietecat, J.P. van Vooren, A. Drowart, J.C. Yernault, F.J. Legros (1993) Disposition of liposomal gentamicin following intrabronchial administration in rabbits. <i>Journal Microencapsulation</i> 10(1): 77-88.
CO	M. Antos, E.A. Trafny, J. Grzybowski (1995) Antibacterial activity of liposomal amikacin against <i>Pseudomonas aeruginosa</i> in vitro. <i>Pharmacological Research</i> 32(1/2): 84-87.
CP	R.M. Schiffelers, G. Storm, I.A.J.M. Bakker-Woudenberg (2001) Therapeutic efficacy of liposomal gentamicin in clinically relevant rat models. <i>International Journal Pharmaceutics</i> 214: 103-105.
CQ	L.E. Bermudez, A.O. Yau-Young, J.-P. Lin, J. Cogger, L.S. Young (1999) Treatment of Disseminated <i>Mycobacterium avium</i> Complex Infection of Beige Mice with Liposome-Encapsulated Aminoglycosides. <i>Journal Infect. Dis.</i> 161: 1262-1268.
CR	J.H. Zhang and J.B. Zhu (1999) A Novel Method to Prepare Liposomes Containing Amikacin. <i>Journal Microencapsulation</i> 16(4): 511-516.
CS	S. Zeng, C. Hu, H. Wei, Y. Lu, Y. Zhang, J. Yang, G. Yun, W. Zou, B. Song (1993) Intravitreal Pharmacokinetics of Liposome-encapsulated Amikacin in a Rabbit Model. <i>Ophthalmology</i> 100: 1640-1644.
CT	M.H. Cynamon, C.E. Swenson, G.S. Palmer, & R.S. Ginsberg (1989) Liposome-Encapsulated-Amikacin Therapy of <i>Mycobacterium avium</i> Complex Infection in Geige Mice. <i>Antimicrobial Agents and Chemotherapy</i> 33(8): 1179-1183.
CU	R.M. Fielding, L. Moon-McDermott, R.O. Lewis, M.J. Horner (1999) Pharmacokinetics and Urinary Excretion of Amikacin in Low-Clearance Unilamellar Liposomes after a Single or Repeated Intravenous Administration in the Rhesus Monkey. <i>Antimicrobial Agents and Chemotherapy</i> 43(3): 503-509.
CV	K. Yanagihara (2002) Design of anti-bacterial drug and anti-Mycobacterial drug for drug delivery system. <i>Current Pharmaceutical Design</i> 8: 475-482.
CW	T.C. Whitehead, A.M. Lovering, L.M. Cropley, P. Wade, R.N. Davidson (1998) Kinetics and Toxicity of Liposomal and Conventional Amikacin in a Patient with Multidrug-Resistant Tuberculosis. <i>Eur J Clin Microbiol Infect Dis</i> 17: 794-797.
CX	E. A. Petersen, J.B. Grayson, E.M. Hersh, R.T. Dorr, S.-M. Chiang, M. Oka, R.T. Proffitt (1996) Liposomal amikacin: improved treatment of <i>Mycobacterium avium</i> complex infection in the beige mouse model. <i>Journal Antimicrobial Chemotherapy</i> 38: 819-828.
CY	A.A. Roehrborn, J.F. Hansbrough, B. Gauldoni, S. Kim. (1995) Lipid-based slow-release formulation of amikacin sulfate reduces foreign body associated infections in mice. <i>Antimicrobial Agents Chemotherapy</i> 39: 1752-1755.
CZ	S.B. Howell (2001) Clinical applications of a novel sustained-release injectable drug delivery system: Depofoam Technology. <i>Cancer Journal</i> 7: 219-227.
CA1	A. Omri & M. Ravaoarinoro (1996) Comparison of the Bactericidal Action of Amikacin, Netilmicin and Tobramycin in Free and Liposomal Formulation against <i>Pseudomonas aeruginosa</i> . <i>Chemotherapy</i> 42: 170-176.

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CB1	✓	L. Kesavalu, J.A. Goldstein, R.J. Debs, N. Duzgunes, P.R.J. Gangadharam (1990) Differential effects of free and liposome encapsulated amikacin on the survival of Mycobacterium avium complex in mouse peritoneal macrophages. Tubercle 71: 215-218.	
CC1	✓	W.E. Bucke, S. Leitzke, J.E. Diederichs, K. Bomer, H. Hahn, S. Ehlers, and R.H. Muller (1997) Surface-Modified Amikacin-Liposomes: Organ Distribution and Interaction with Plasma Proteins. Journal Drug Targeting 5(2): 99-108.	
CD1	✓	S. Ehlers, W. Bucke, S. Leitzke, L. Fortmann, D. Smith, H. Hansch, H. Hahn, G. Bancroft, and R. Muller (1996) Liposomal amikacin for treatment of M. avium Infections in clinically relevant experimental settings. Zbl. Bakt. 284: 218-231.	
CE1	✓	E.K. Kim and H.B. Kim (1990) Pharmacokinetics of intravitreally injected liposomes encapsulated tobramycin in normal rabbits. Yonsei Medical Journal 31(4): 308-314.	
CF1	✓	A. Omri, C. Beaulac, M. Bouhajib, S. Montplaisir, M. Sharkawi, J. Lagace (1994) Pulmonary retention of free and liposome-encapsulated tobramycin after intratracheal administration in uninfected rats and rats infected with Pseudomonas aeruginosa. Antimicrobial Agents and Chemotherapy 38(5) 1090-1095.	
CG1	✓	J.R. Morgan and K.E. Williams (1980) Preparation and properties of liposome-associated gentamicin. Antimicrobial Agents and Chemotherapy 17(4) 544-548.	
CH1	✓	P. Lutwyche, C. Cordeiro, D.J. Wiseman, M. St-Louis, M. Uh, M.J. Hope, M.S. Webb, B.B. Finlay (1998) Intracellular delivery and antibacterial activity of gentamicin encapsulated in pH-sensitive liposomes. Antimicrobial Agents and Chemotherapy 42(10) 2511-2520.	
CI1	✓	R.M. Schiffelers, G. Storm, M.T.T. Kate, L.E.T. Stearne-Cullen, J.G. Den Hollander, H.A. Verbrugh, I.A.J.M. Bakker-Woudenberg (2001) In vivo synergistic interaction of liposome-coencapsulated gentamicin and ceftazidime. Journal Pharmacology Experimental Therapeutics 298(1): 369-375.	
CJ1	✓	A.I. Vitas, R. Diaz, and C. Gamazo (1996) Effect of composition and method of preparation of liposomes on their stability and interaction with murine monocytes infected with Brucella abortus. Antimicrobial Agents and Chemotherapy 40(1) 146-151.	
CK1	✓	E.A. Trafny, M. Stepinska, M. Antos, J. Grzybowski (1995) Effects of free and liposome-encapsulated antibiotics on adherence of Pseudomonas aeruginosa to collagen type I. Antimicrobial Agents and Chemotherapy 39(12) 2645-2649.	
CL1	✓	S.P. Klemens, M.H. Cynamon, C.E. Swenson, R.S. Ginsberg (1990) Liposome-encapsulated-gentamicin therapy of Mycobacterium avium complex infection in beige mice. Antimicrobial Agents and Chemotherapy 34(6) 967-970.	
CM1	✓	S. D. Nightingale, S.L. Saletan, C.E. Swenson, A.J. Lawrence, D.A. Watson, F.G. Pilkiewicz, E.G. Silverman, S.X. Cal (1993) Liposome-encapsulated gentamicin treatment of Mycobacterium avium-Mycobacterium intracellulare complex bacteremia in AIDS patients. Antimicrobial Agents and Chemotherapy 37(9) 1869-1872.	
CN1	✓	C.E. Swenson, K.A. Stewart, J.L. Hammett, W.E. Fitzsimmons, R.S. Ginsberg (1990) Pharmacokinetics and in vivo activity of liposome-encapsulated gentamicin. Antimicrobial Agents and Chemotherapy 34(2) 235-240.	
CO1	✓	I.A.J.M. Bakker-Woudenberg, M.T. ten Kate, L.E.T. Stearne-Cullen, M.C. Woodle (1995) Efficacy of gentamicin or ceftazidime entrapped in liposomes with prolonged blood circulation and enhanced localization in Klebsiella pneumoniae-infected lung tissue. Journal Infectious Diseases 171:938-947.	
CP1	✓	M.W. Fountain, S.J. Weiss, A.G. Fountain, A. Shen, R.P. Lenk (1985) Treatment of Brucella canis and Brucella abortus in vitro and in vivo by stable plurilamellar vesicle-encapsulated aminoglycosides. Journal Infectious Diseases 152(3): 529-535.	
CQ1	✓	C.I. Price, J.W. Horton, C.R. Baxter (1992) Liposome delivery of aminoglycosides in burn wounds. Surgery, Gynecology & Obstetrics 174: 414-418.	

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	CR1	C.I. Price, J.W. Horton, C.R. Baxter (1994) Liposome encapsulation: a method for enhancing the effectiveness of local antibiotics. Surgery, 115(4): 480-4487.	
	CS1	C.I. Price, J.W. Horton, C.R. Baxter (1989) Enhanced effectiveness of intraperitoneal antibiotics administered via liposomal carrier. Arch Surgery 124: 1411-1415.	

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